

Development and evaluation of an integrated electronic data management system in a South African metropolitan critical care service

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Introduction: The importance of accurate healthcare data is vital when approaching current healthcare challenges, but is difficult to collect in busy, under-resourced environments. It was aimed to develop and implement an information system that is cost-effective, easy and practical for data collection. A clinically integrated data collection system that demonstrates how to achieve this in a resource-poor setting is described.

Methods: A database was developed using customisable software to provide a robust relational database and clinically practical solution to data collection. The system was examined for data completeness through a field audit of referral records for evaluation of the reviewed system.

Discussion: The database system has been incorporated into the daily flow of clinical work, thus reducing duplication of note keeping and avoiding the need for data capturers. After improving the design and user interface, better compliance was noted. This provided useful insight into critical care database development.

Conclusion: This project has demonstrated successful development and implementation of a hybrid electronic medical record and registry for a critical care metropolitan service. It has provided a practical information system allowing for the development of local critical care services with the ability for quality improvement, aggregate reporting for systems planning, and research.

Keywords: critical care, database, developing country, ICU, registry

Introduction

Critical care medicine is a developing speciality in South Africa (SA). Increasing pressure on healthcare budgets and the implementation of the National Health Insurance¹ necessitates an evaluation of current intensive care unit (ICU) practices and resources. The importance of accurate healthcare data is critical in tackling these challenges and presents several advantages.² These data may be used for provincial, national and international improvements, including performance evaluation, quality improvement and aggregate reporting for systems planning. It should also aim to improve clinical practice and patient care, and enable research. We aimed to develop and implement a system that is cost-effective, easy and practical for data collection and one that would allow us in the future to achieve these goals as listed above.

Several electronic medical registries have already been developed, such as the United Kingdom Intensive Care National Audit and Research Centre (ICNARC) Case Mix Program Database,³ the French intensive care databases Collège des Utilisateurs de Bases de données en Réanimation (Cub-Réa) and OutcomeRea, the United States National Registry of Cardiopulmonary Resuscitation,⁴ the PROGRESS sepsis registry⁵ and the Australian and New Zealand Intensive Care Society Adult and Paediatric Databases.⁶ However, sustainability of this kind of information system and analysis for a developing country is limited by acquisition of an electronic database system and human resources for data collection, input and coding. These financial implications and resource demands make such systems

seemingly unachievable in low- and middle-income countries,⁷ with some progress made locally.⁸

We identified the opportunity to develop a new system that would work in a developing world setting. We will proceed to explain the development and integration process of this clinical workflow database. It provides a novel and practical solution to data collection in our setting and we propose this to be a viable project for the critical care community in SA.

Setting

Medical records in our critical care service are traditionally handwritten and vary widely from being meticulous to casual and illegible. These stored records are often lost or incomplete, causing significant problems should they need to be retrieved for medico-legal purposes, audit or research. The practice of manual data collection, storage and analysis is laborious. The burden of a large clinical workload, training and development of critical care has made it difficult for quality improvement and research to achieve the focus it deserves. This has been influenced by the tedious nature of manual collection, storage and analysis. There is a need to improve both the quality of the record and the collection and storage techniques of data to enable quality improvement, systems planning and research.

Our objective was to create a solution that meets both the requirements of a medical record and that of a registry or database. The purpose of a medical record, to document the patient's medical care during an episode of illness, can be

improved by the introduction of an electronic format that offers the benefit of standardising data entry points. By definition, a database is any structured collection of records that allows meaningful data collection and can be used for a number of reasons. This is usually referred to as a registry. A registry may also be defined as a systematic collection of clearly defined data for patients with specific health characteristics held in a central place for a predefined purpose to improve and monitor quality of care or as a resource for research.⁹

Electronic databases are flexible and easy to access. This is advantageous compared with manually recorded documents. Our goal was to create an electronic system that replaced the written record, not burdening the end-user with additional work, and without the need to employ data capturers.

Methods

Analysis

Our metropolitan critical care system is made up of a regional hospital with nine beds and a tertiary hospital with six beds. The current set-up is staffed on a rotational basis by registrars and medical officers. Critical care specialists, fellows or consultant anaesthesiologists support definitive management and decision-making processes. There are no data capturers in either hospital. The electronic solution had to take into account the high clinical workload in both units. Ideally the data entry should follow the clinical workflow. The hospitals still require paper records and thus duplication of records and paperwork would be counterproductive.

Initial ethical approval for the database development was granted through the local hospital ethics committee. The Bioethics Research Committee of KwaZulu Natal Ethical granted class approval (BCA211/14) for implementation in the Metropolitan.

Synthesis

The development of the database was achieved using FileMaker Pro® software (FileMaker Inc., Santa Clara, CA, USA). This software operates across different platforms, combining a graphical user interface with an application, allowing for relational database building. This enables the database to be uniquely structured. Additional benefits include its ability to be used in a variety of settings such as desktop, server, mobile devices and web-delivery configurations.

A relational database is an associated collection of tables that allows access between the tables.¹⁰ This is practical in the medical setting and avoids the need for the duplication of data entries, for example rewriting a patient’s name at a number of critical events during the clinical course. Deciding on those critical clinical events is part of object modelling and this is achieved by processing the real-life situation into tables and associations between the tables and fields. Tables consist of named columns and data captured in each column are called a field. Each patient record is a row in the table. The role of the developer is to determine the priority and importance of particular tables or fields, how they are expressed, how they relate to each other and how one navigates between them.

This database was divided into clinical workflow components, namely the referrals and admissions/discharges. These components formed the main tables in the database. This design was necessary to enable the database entries to match the clinical flow of the patient through ICU. The relationship of these tables is seen in Figure 1. The data fields required were discussed and

decided on by the intensivists working in the Metropolitan. Data were divided into those representing information for medical record purposes and those for registry purposes. Free text could be written into certain fields for medical record purposes. The ability to print patients’ medical notes allowed for the obvious advantage of legibility. The disadvantage is the inconsistency of data in the free text field. Data fields for registry purposes offered predetermined answers including options for electing one or multiple answers. Although this design is prescriptive it allows for better interpretation and quicker data entry.

The main screen, referred to in our system as the dashboard, is seen in Figure 2. This is the entry point into the database for all users. The two boxes seen on this layout are portals and represent ‘Referrals’, for which no final decision on admission or refusal has been made, and ‘Admissions’. Portals allow navigation into patient records by clicking on their name, thus avoiding potential errors by incorrectly typing names or reference numbers. Once a decision has been made to admit a patient, an admission record is generated. The patient name is removed from the ‘Referrals’ portal and subsequently appears on the ‘Admissions’ portal. In addition the ‘Referrals’ portal serves as a reminder that a final decision has not yet been made for the patient. This assists with follow-up and prevents patients being lost to follow-up, which may occur with verbal or written handover systems. Clinical events can be entered for admitted patients (Figure 3), for example an Apache II score or a daily entry that captures predetermined data for unit statistics (for example number of ventilator days). Weekly reports are automatically generated for the unit’s morbidity and mortality meetings. This report provides an opportunity to check data integrity. Missing data can then be added as an amendment into the patient’s record to ensure completeness.

Protection of patient information is an integral element of an electronic database. Access to the database is password protected and user names and passwords are given to each user by the developer for the duration of their ICU rotation. Patient details are linked to a unique identification number generated by the database. This number is then used for each data entry point to link data to a particular patient.

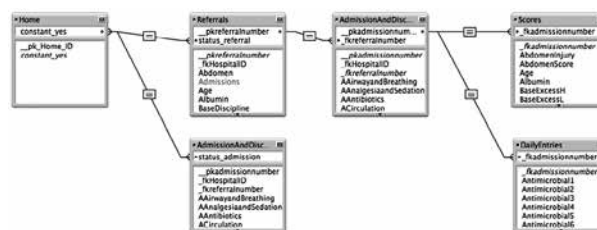


Figure 1: Relationship of database tables.



Figure 2: Dashboard interface.

Figure 3: Layout for choice of clinical event.

Implementation

The developer trained clinical staff at the beginning of their rotation. Initial training consisted of a one-hour session. Ongoing communication and troubleshooting with the end users provided useful information for refining the user interface. In the event of hardware or software problems, paper templates are used to ensure continuation of clinical care and these are later transcribed into the system. The first system was installed in a single intensive care unit in July 2012 at Greys Hospital ICU. This was succeeded by an upgraded system in November 2013 based on lessons learnt through its use and evaluation. The second system provided a more robust database with more intuitive navigation and less room for error.

Evaluation

The system has been reviewed for data completeness and identification of problem areas through a field audit of the referral records. The first database ran over an 18-month period from May 2012 to October 2013 with a total of 1 119 referral records. The revised database had run for 12 months at the time of the audit (November 2013 to October 2014) with 1 378 referral records. Removal of incorrect records, which include duplicates and empty records, left 1 131 and 1 056 actual patient records in the first and revised systems. There is an error rate of 6 and 2% respectively (Table 1).

The significant difference between admission statistics for the two systems could be attributed to a number of factors. The initial database was the first electronic-based medical record system introduced into the ICU. A transition period between the traditional paper-based format and the new electronic system resulted in a gradual integration into clinical practice. This

Table 1: Comparison between first and revised solutions

	First	Revised
Duration	18 months	5 months
Dates	May 2012– October 2013	November 2013– October 2014
Total referral records	1 119	1 378
Incorrect records (duplicates or empty)	63 (6%)	43 (2%)
Total patient records	1056 (59/month)	1131 (94/month)
Total fields in the referral record	69	64
Fields excluded for evaluation of data completeness	19	10
Types of fields used in data evaluation: total	50	54
Free text	29	31
Drop down	9	15
Tick boxes	8	4
Radio buttons	4	4

Table 2: Comparison of data omissions

	First	Revised
Omissions by field type (in %)	Average = 29	Average = 18
Free text	35	34
Drop down	19	17
Tick boxes	14	17
Radio buttons	42	5
Omissions by data type (in %)	Average = 29	Average = 18
Patient details	61	5
Diagnosis	45	23
Referral details	23	13
Clinical data	7	36
Decision	9	5
Management	29	30

improved over time until eventually all referrals were captured using the electronic system. By the time the revised version of the database was introduced, the system was well established and no patient records were lost. The necessary paperwork generated serves as proof that the patient has been entered onto the system.

There are four varieties of fields, namely free text, drop-down menus, tick boxes and radio buttons. There were a similar number of fields in each version of the database, 69 in the first versus 64 (see Table 1). A number of fields were not included in this data completeness audit due to the field being calculated, generated or copied from another table or part of the database. The different types of fields in the two systems are comparable, with predominance in drop-down fields in the revised system.

The omission of data by field type is represented in Table 2. The omissions by data type were examined and the data were divided into six categories: patient details, diagnosis, referral details, clinical data, decision and management. The data included in each of these groups are represented in Appendix 1. In the first system radio buttons (42%) and free text (35%) were the most often omitted fields with patients details (61%), diagnosis (45%) and management (29%) the most omitted of the data-type field. The revised systems showed free text to remain as the most omitted field type (34%) and clinical data (36%), management (30%) and diagnosis (23%) the most omitted data types. There was an overall reduction in omissions from 29% to 18% in the revised system.

Discussion

Due to resource constraints and the lack of data capture tools, it was essential for the database to be made part of the daily activities of the doctors working in the unit in order for this project to succeed. A paper record was needed at the stages of referral and evaluation, admission and discharge. The data entry points and fields were designed to match these clinical events. The written notes in the patients' files were replaced with a printed version from the database, negating duplication of tasks. The patient medical record was made electronic and then the program generated the needed paperwork, making the process efficient. The structural layout of the database was improved through consultation with users. This significantly improved data capturing (up to 12%) and made the system more robust.

Changing the way the data were expressed (in both the architectural design and the user interface) resulted in improved compliance in three out of the four field types and four out of the six data types. For example, in the first version of the database the entry point was the patient profile, which included name, date of birth, age and gender of the patient with an allocated patient identification number. All further entries, namely referral, admission, summary and discharge, were tables linked to the patient profile. Each entry thus included a number of steps to perform a referral for the patient: enter a new patient profile, enter a referral for that patient and finally complete the decision to admit or not to admit the patient. In the revised database the number of steps was reduced by making the patient referral the entry point. This more accurately reflected the clinical flow and contributed to better compliance. The patient details, details of the referral and decision for admission are now in a single table with one layout. This allows a single entry of all the data needed for the electronic recording of the patient referral. This reflects a more logical flow of data and allows easier implementation for the user. Drop-down menus and tick-box-type fields performed consistently well in both databases and where possible fields should be restricted to one of these options for improved compliance.

Evaluation of the fields by data type showed that compliance was better in all categories except for the clinical data. This is likely due to the increased number of fields in this category in the revised database. The first database included only vital signs, whereas the revised database has blood gas results, haematological and biochemical data included. These results may not always be available at the time of the referral and returning later to add the data does not seem practical.

Through the use of local programming expertise, existing hardware and the purchasing of cost-effective software, several barriers to development and introduction of an integrated information system have been overcome. The result is a database interface that is user friendly and data required for entry are

simple and uncomplicated compared with other patient diagnostic coding systems. Prospective paperwork is generated to meet the needs of the hospital and has encouraged the end-user to accept and incorporate the system into their daily work. The combination of both free text and predetermined choices in fields offers reasonable data acquisition without being exhaustive for the user, thus promoting compliance.

There are a number of limitations to the information system. The developer needs to be onsite in the initial phase of user training to manage problems; however, the time required for training users to a competent level is short. The need for such training may make expansion difficult, although this may be overcome through pre-recorded video sessions (internet based for wider access) and trouble-shooting menus. Attempts to identify and overcome associated challenges with the database are addressed in Table 3. Due to the pilot nature of this project, data fields were not made mandatory, allowing the user to leave out information. This choice was made to allow clinical workflow to continue if there was an information system problem. The logic here was for the users to find the system quick and easy to use. It does, however, rely on user integrity for compliance and may lead to missing data. With the establishment of the information system as part of the clinical administrative work, the next step in development is to make fields compulsory.

Since the introduction of this information system in the intensive care unit, the benefits have clearly been evident. To date there has been no reliable, accessible knowledge of basic unit statistics — for example patient mix, diseases, length of stay or severity scoring. Review of this information through the database has enabled assessment of quality of care, a review of the demand for ICU beds in the Metropolitan, and easily accessible records for medico-legal cases.

Conclusion

Integration of a medical registry into clinical workflow is important for sustainability and time management. Combining

Table 3: Pitfalls in the system

Pitfall	What we did	Planned improvement
User computer literacy	Reasonable literacy amongst staff. For those that have poor literacy repeated training sessions are given for reinforcement	Control over basic skills is limited; the aim is to simplify the system for even the most inexperienced user
User training on the system	A single training session of 1 hour is sufficient for most users. The developer is available for problem solving and assistance. However, only a single person available is the limiting factor and may hamper sustainability	Manual to be developed with frequently asked questions. Video recording of training session (access to the video via the internet)
Expansion	Single computer is now expanded to two through local networking. Different sites are not networked therefore changes need to be done manually at both sites	Need internet or server connectivity
System complexity	The system is user friendly and intuitive to use	Suggestions are taken into account for future improvement
Design	Development was done by ICU staff members. This enables good understanding of the clinical flow and the electronic system matches this closely	
Data quality & completeness	Non-obligatory fields to prevent hampering of clinical workload but data are therefore not 100% complete	Fields to be made obligatory
Buy in from users (perceived benefit)	The electronic system prints all needed paperwork such as referral record, admission and discharge. Clinical work cannot proceed without these forms making minimum data entry necessary. System was well integrated and made documentation easier for the doctors	
Dependence on individual	A single developer with good knowledge of the program is not sustainable	Consolidate training of permanent senior staff
Back up system	Regular system backups performed.	
System security	Password protected access	
Power supplies	Central power source reliable. Reliable paper trail ensures electronic data capture in the event of a power failure	
Technical support	Onsite developer, contactable via email or telephonically. Low sustainability	Consolidate training of permanent senior staff

data input for patient care and for registry purposes, aggregate reporting and research is a practical way in which to overcoming the potential problem of longevity of a database in a high clinical workload environment of low- and middle-income countries. As demonstrated in this project, it is possible to provide a system in which both clinical care and data collection are achieved and may even reduce workload by avoiding duplication of work.

The features of this system were designed and constructed by a clinician without previous programming capabilities or training. This registry uses heuristic software and was designed for point of care data entry by the clinician. This project shows successful development and implementation of a hybrid electronic medical record and registry for our critical care metropolitan service. This has provided a practical foundation for further advancement of an information system as well as development of local critical care medicine by producing the ability for quality improvement, aggregate reporting for systems planning and research.

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Appendix 1:

Data groups with included fields

Patient details	Diagnosis	Referral details	Clinical data	Decision	Management
First name	Type	Emergency/elective	History	Final outcome (admitted or not admitted)	Management plan
Last name	Organ system		Examination		
Date of birth		Date referred			
Gender		Time referred	Pulse		
Age		Time seen by ICU	Systolic		
Race		ICU registrar	Diastolic	Delay	
	Details		Respiratory rate		
		ICU consultant		Reason for delay	
		Operative status	GCS		
		Base discipline	Urine output	Reason never admitted	
		Discipline consultant	Haematocrit		
		Referring doctor	White blood cells	Unit transferred to	
		Discipline referring doctor	Sodium		
			Urea		
Comorbidities		Referral hospital	Creatinine		
		Referral reason	Albumin		
		Current patient location	Bilirubin	Date/time of final decision	
		Days in hospital	Glucose		
		Currently ventilated	FiO2		
			pH		
		Previously in ICU	pCO2		
		SCCM	pO2		
			Lactate		